

## **REMARKS**

### **I. EXAMINER INTERVIEW**

Applicant wishes to thank Examiner Leith for the courtesy she extended to Applicant's representatives during a personal interview on January 23, 2008. This response is filed further to that interview in addition to the pending Office Action.

In addition to the issues discussed during the interview, Applicant wishes to state that contrary to Examiner's position, the instant invention is not directed to simple fruit or vegetable extracts or methods of use thereof. In fact, none of the pending claims recites or employs any extraction process. Rather, Applicant's discovery is a novel method that transforms a fruit and/or vegetable pulp to a fruit and/or vegetable derived composition having therapeutic and/or cosmetic properties. In at least this aspect of the invention, the claims are directed to methods of making such compositions, as long as the fruit or vegetable is capable of being pulped. Therefore, the novelty of the method of making (process) claims resides in the inventive steps taken to prepare the product and not the source of fruit or vegetable employed.

In another aspect of the instant invention, inventor claims *inter alia* a method of treating a patient diagnosed with specific set of conditions recited in the claims or at risk of developing such conditions, wherein the method comprise administering to the patient an effective amount of the composition obtainable by the claimed method of making. Finally, the instant invention is also directed to products obtainable by the methods that are used to prepare the therapeutic composition.

### **II. STATUS OF THE CLAIMS**

Upon entry of this response, claims 1 to 7 and 10 to 46 are pending. Claims 8 and 9 are canceled without prejudice. Claims 12 to 46 are added. Claims 1, 2, 4, 5, 7, and 10-11 are amended to better define the invention. Support for amendments in the claims and new claims are found in the original claims and page 5, line 20, page 5, line 32 to page 6, line 2, page 6, lines 8-16 and 20-27, page 8, line 15 to page 10, line 33. No new matter is added.

In the Office Action, Examiner has rejected the claims 1-11 for various reasons. Examiner has also declared claims 8-11 free of art. Accordingly, Applicant's response is

prepared to embrace the features of original claims 8-11 that are declared to be free of art. Applicant respectfully requests withdrawal of all rejections in view of the amended claims and the remarks below.

### **III. REJECTION UNDER 35 U.S.C. § 101**

The Examiner has rejected claims 8-9 as lacking steps involved in the process and being in an improper process claim format. *see* OA at pg. 2.

Claims 8-9 have been canceled. Corresponding claims 10 and 11 are written in proper process claim format. Therefore, Applicant requests withdrawal of this rejection.

The Examiner has rejected claims 8 and 10 asserting that these claims are broad enough to read on prevention of skin cancer.

Notwithstanding that the breadth of a claim should not be at issue for a proper analysis under 35 U.S.C. § 101, Applicant nevertheless has amended the claims to better define the scope of the invention. Accordingly, claim 10 is now directed to a method of treating or prophylactically treating a patient suffering from a specific skin condition. Claim 8 has been cancelled. Applicant requests withdrawal of this rejection.

### **IV. REJECTIONS UNDER 35 U.S.C. § 112**

#### **A. REJECTION UNDER 35 U.S.C. § 112, 2<sup>ND</sup> PARAGRAPH**

The Examiner has rejected claims 8-9 asserting that they do not set forth any steps involved in a process. Claims 8-9 have been canceled, therefore, this rejection is moot.

#### **B. REJECTION UNDER 35 U.S.C. § 112, 1<sup>ST</sup> PARAGRAPH**

##### **I. WRITTEN DESCRIPTION**

The Examiner has rejected claims 1-11 that recite, or depend upon such claims that recite, “heating a fruit and/or vegetable pulp” or “vegetable derived composition” or is a method for using a composition which states “fruit and/or vegetable derived composition,” because the Examiner deems that Applicant has not set forth a representative number of examples in order to reasonably verify possession of such a potentially enormous number of fruits and/or vegetable products. *see* OA at pg. 4 ¶ 2. Specifically, Examiner argues that “it is unquestionable that the

claims are broad generics, with respect to all fruits and/or vegetables. The possible variations of products are limitless.” *see* OA pg. 4.

Applicant states that the Examiner’s rejection is not proper, specifically in view of the newly amended claims. Nevertheless, for purposes of addressing the Examiner’s concerns the following arguments are set forth herein.

Applicant respectfully states that “the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the subject matter being claimed by the inventor.” *Vas-Cath Inc. v. Mahurkar* 935 F.2d 1555, 1563 (Fed. Cir. 1991). “If the written description does not use precisely the same terms used in a claim, the question then is whether the specification directs or guides one skilled in the art to the subject matter claimed such that the specification reasonable convey to those skilled in the art that the inventor invented what is claimed.” *Fujikawa v. Wattansin*, 93 F.3d 1559, 1570 (Fed. Cir. 1996). To better assist the patent bar the USPTO published the Written Description Guidelines of 2001 in Federal Registry, vol. 66. No 4, January 5, 2001. (“USPTO Guidelines”).

Applicant respectfully submits that the instant Specification complies with the USPTO Guidelines and the rules as it provides *sufficient distinguishing identifying characteristics of the genus of fruits or vegetables*, that can be employed for the instant claims. The newly amended claims are directed to products and methods of making and using such products. Contrary to the Examiner’s position, neither the case law, nor the USPTO Guidelines require a Specification to list the entire species within a claimed genus.

All that is required to satisfy the written description requirement of section 112 is whether one skilled in the art can reasonably conclude that the inventor was in possession of the claimed invention at the time the application was filed. The USPTO Guidelines enumerates several factors to be considered for a proper written description rejection under 35 U.S.C. § 112 first paragraph, none of which states that all species within a claimed genus should be listed *ipsis verbis* in a Specification for it to meet the written description requirement.

It appears that in this case, the Examiner is mostly concerned with the breadth of the language “fruit and/or vegetable derived.” The Examiner states that this limitation leads to limitless number of possible products and that the Specification does not adequately disclose

such sufficient number in comparison to the size of the genus of “fruits and vegetables.” *see* OA pg. 4.

In response, Applicant respectfully states that the Examiner is not properly applying the written description inquiries set forth in the USPTO Guidelines. The Guidelines specifically refer to the following factual inquiries for purposes of determining whether a given specification has adequate written description: (1) complete disclosure of a complete or partial structure, (2) physical or chemical properties, (3) functional characteristics, (4) structure/function correlation, (5) methods of making the product, or (6) any combination thereof. Only after an Examiner has analyzed such factual inquiries could a written description rejection be proper. The Examiner has merely failed to show any such analysis.

Applicant addresses each factor inquiry to establish that Applicant was in possession of the instant invention at the time the application was filed:

**(1) DISCLOSURE OF A COMPLETE OR PARTIAL STRUCTURE**

The instant disclosure satisfies this factual inquiry. Not only does the Specification describes various sources of vegetable and fruits at pages 4-6, including about 35 specifically named examples, but also the Specification also provides for at least 14 different fruits or vegetables in 35 working examples. *see* Specification at pgs 11-39. Examiner states that Applicant has disclosed several types of fruits and/or vegetables as listed on page 4 of the instant specification. Yet, Examiner adds that the instant disclosure teaches only a “very few number in comparison to the enormous types of fruits and vegetables actually known.” *see* OA at pg. 4, ¶ 3.

In response, Applicant points out that to adequately show possession of any given genus, the written description guidelines do not impose a requirement for disclosing any minimum number of species. This fact is assessed on a case-by-case basis. In the instant case, at least 14 different and distinct species of fruits or vegetables have been exemplified. Each of such species possess divergent natural and therapeutic characteristics. The Specification further teaches at least about 20 other fruits or vegetables that can be used according to the instant invention. Thus, the Specification at least provides an adequately description of a partial structure for the genus of suitable fruits or vegetables that can be employed in the claimed invention. For such reason alone, the written description rejection should be withdrawn.

**(2) PHYSICAL OR CHEMICAL PROPERTIES**

The instant disclosure satisfies this factual inquiry. The instantly claimed invention is based on using pulped vegetables or fruits. *see* Specification at pg. 4, line 3-4. The pulp by itself is a well-defined and recognized term of art. The process of pulping is well defined in the art and the Specification. The Specification explicitly exemplifies how to obtain the pulp of a fruit and in numerous sections describes various physical or chemical properties of the desired characteristics of the genus of vegetables and fruits. *see* pg. 4, line 5 to pg. 6, line 5; pg. 11, lines 9-15, Examples 1-35. Thus, fruits and vegetables with a defined set of physical or chemical properties, capable of being pulped, do share common physical characteristics suitable for the instant invention.

For example, at page 4, line 5, the Specification states that “pulp of a vegetable or fruit can be derived from an inner fleshy part of the fruit or vegetable or alternatively, from a mixture of skin and outer fleshy part of fruits or vegetables.” At page 5, line 25, the Specification provides a definition for “vegetable or fruit pulp.”

The working examples teach at least 14 fruits or vegetables that were subject to the claimed process. Specific examples include paw paw, tomato, peach and potato, each of which have entirely distinct and disparate properties and therefore adequately represent the genus of fruits and/or vegetables as a whole. Such teachings sufficiently direct those of ordinary skill in the art to the optimal physical or chemical properties for the vegetable or fruit suitable to be employed in the instant claims.

**(3) FUNCTIONAL CHARACTERISTICS**

The Specification satisfies this factual inquiry. The entire pages 4-6, and 11 describe the functional characteristics of the pulp and enumerates various type of fruits that can be used in the invention. Accordingly, depending on the fruit or vegetable, the envisioned species should be able to be pulped.

**(4) STRUCTURE/FUNCTION CORRELATION**

The Specification satisfies this factual inquiry. At numerous sections Applicant articulates specific fruits and vegetables that can be employed in the instant invention. For example, paragraph example 1 is directed to pawpaw, examples 2-3 are directed to peach, and example 4 is directed to tomato, and example 6 is directed to mango. All such fruits are pulped and/or are capable of being pulped. Thus, the instant disclosure teaches that there is a correlation

between the type of fruit or vegetable candidate and its degree of pulpability. Taken together, these paragraphs suggest that at least the candidate fruits or vegetables within the meaning of the instant invention are necessarily pulped and/or pulvable. Such specific teachings collectively amount to blazemarks sufficient for one of ordinary skill in the art to establish a structure/function correlation .

**(5) METHODS OF MAKING THE PRODUCT**

The Specification satisfies this factual inquiry. Pages 12-39 provide ample description of methods employed to make and use the instantly claimed inventive concept. Accordingly, for at least methods of making all that is needed to be known is that the candidate fruits and vegetables can be pulped and heated.

**(6) ANY COMBINATION THEREOF**

Following the discussion of previous factual inquiries, Applicant asserts that contrary to Examiner's position the instant Specification adequately describe the distinguishing attributes shared by the members of the genus of "fruits and vegetables." Such attributes are described by the way of type of vegetable of fruits that are properly pulped either by their skin, flesh or other parts. *see* Specification at pgs 4-6.

Since all factual inquiries articulated in the USPTO Guideline are adequately described in the instant Specification, Applicant respectfully submits that the invention as claimed was in possession of the inventors at the time of the filing of the application.

Applicant further submits that the USPTO has granted a number of patents recently with broad references to fruits in the claims e.g. US 7,228,793 which refers to a desired quantity of fruit or vegetable matter; US 7,198,811 which refers to preservation of any fruit or vegetable; US 6,855,359 which refers to a process which comprises combining a fruit juice with other ingredients, of which only five are specifically listed; US 7,153,536 which refers to the preparation of a food sauce having a fresh fruit suspension; US 6,623,779 which refers to a method of producing intermediate-moisture formed food products made from a mixture of partially dehydrated fruit or vegetable pieces; and US 7,166,281 (granted by the present Examiner) which is directed to a "pharmaceutical composition for topical application to a site of insect bites and stings to relieve any of itch, pain, and swelling associated therewith, consisting of an effective amount of an abrasive ingredient and a carrier, wherein upon application by a user said composition is able to relieve any of the itch, pain and swelling caused by the insect bites

and stings at said site; wherein said abrasive ingredient is selected from the group consisting of walnut shell, pumice, plastic material, sand, stone, seed shell, fruit shell, seed, metal, chitosan and ground crab shell”. No examples of particular fruit shells are listed in the specification and the only formulation example given recites walnut shells as the abrasive ingredient.

These examples confirm that is not a requirement under the existing USPTO examination practice to list hundreds of specific examples of fruit and vegetables to support a claim that refers generically to fruit and/or vegetables. Applicant also submits that new claim 26 recites fruit and vegetables listed specifically in the Specification as filed at page 4 lines 14 to 19. This claim clearly meets the written description requirements.

## II. ENABLEMENT

The Examiner rejects claims 8-11 as allegedly failing to provide enablement for methods of treating or preventing any dermatological disorders or treating pain or wherein any vegetable/fruit matter is used. *see* OA at pg. 6, ¶ 2. Specifically, the Examiner is concerned with the lack of disclosure as to the active ingredients of the claimed composition. To that effect, Examiner states that “while the active ingredients of Applicant’s extract have not been elucidated, it is clear that the extract contains some unknown active ingredient.” *see* OA at pg. 7, ¶ 2. The Examiner then argues that extraction process of plant matter could lead to different ingredients based on the polarity of the solvent. *see* OA at pgs. 7-9. The Examiner concludes that due to the enormity of possible extraction permutations, the nature and content of the plant extract is unpredictable and as the subsequent combination of ingredient’s working synergistically to provide a therapeutic effect would also be unpredictable. *see* OA at pg. 11, ¶ 1. Finally, Examiner states that the exemplified method of treating psoriasis, scarring and pain “do not provide a nexus with respect to various other skin ailments such as skin cancer, eczema, acne, rosacea, warts and ulcers...” *see* OA at pg. 12, ¶ 2.

As an initial matter, without prejudice or disclaimer of the previously claimed subject matter, in the interests of expediting allowance of this application, Applicant has limited the independent method of use claims, claims 10 and 11 and new claims 12 to 19, to refer to a subset of disorders. As the claimed disorders share a common pathophysiology, it is reasonable to one of ordinary skill in the art to practice the entire scope of the claims as presented, once in possession of the instant specification. Moreover, again without prejudice or disclaimer of the claimed subject matter, and in the interests of expediting allowance of this application, claims 10

to 19 are also limited to paw paw, which the examiner indicated was allowable, optionally in combination with one or more other fruits and/or vegetables, thus for at least such reasons the rejection should be withdrawn.

**V. REJECTION UNDER 35 U.S.C. § 102(B) OVER BURCHARD, H. REPORTING FOR THE WASHINGTON POST (1999).**

The Examiner has rejected claims 1, 4, and 6 over Burchard alleging that Burchard taught the recipe to pawpaw fruit jam which included combining pawpaw pulp, water, applesauce, apple juice, lime juice, sugar and pectin, stirring and bringing to a boil. *see* OA at pg. 14, ¶2.

It is well established that “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described in a single prior art reference.” *Verdegall Bros. v. Union Oil Co. of California*, 814 F.2d 618, 631 (Fed. Cir. 1987). “There must be no difference between the claimed invention and the reference disclosure as viewed by one of ordinary skill in the art.” *Scripps Clinic & Research Fdn. V. Genentech*, 927 F.2d 1565, 1576 (Fed. Cir. 1991). In this case, Burchard simply does not teach every element of the rejected claims.

The instant claims as amended are directed to a process for making a fruit and/or vegetable composition comprising the steps of: (a) preparing a pulp from one or more fruit(s) and/or vegetable(s); (b) heating the fruit and/or vegetable pulp up to a temperature in the range of about 40° C to 100° C; and (c) mixing between about 1 and 40% w/w of a mild base having a pK<sub>a</sub> of less than 11 with the heated fruit and/or vegetable pulp whilst said pulp has a temperature in the range specified in step (b).

Burchard simply does not teach all the elements of the instantly claimed limitations. Specifically, Burchard does not teach the use of any base having a pK<sub>a</sub> of less than 11. Examiner has argued that water meets the limitation of a mild base, however, water has a pK<sub>a</sub> of about 15 and does not meet such limitation as currently presented. *see* Exhibit 1.

Similarly Burchard also fails to meet the limitations of product-by-process claim 6. The process of claim 1, which defines the product of claim 6, requires the addition of a mild base having a pK<sub>a</sub> of less than 11. This will inevitably have the effect of increasing the pH of the final product. For example, the addition of sodium bicarbonate to paw paw in Example 1 of the instant Specification leads to a final pH of 8. By contrast, Burchard is concerned with the



production of a jam, which is an acidic food product having a pH of from about 3.5 to about 4.5. (see Exhibit 2, a printout of a US Food and Drug Administration listing of the pH of common food products: <http://www.cfsan.fda.gov/~comm/lacf-phs.html>). Further, Burchard describes the addition of lime juice and apple juice, both of which are acidic. There is no disclosure by Burchard of the addition of a base having a pKa of less than 11. Accordingly, a jam produced by the process described by Burchard is clearly not a product that could result from the process of instant claim 1. Therefore, Burchard fails to anticipate claim 6.

In view of such reasons, this rejection should be withdrawn because Burchard fails to teach each and every element of the instant claims.

**VI. REJECTION UNDER 35 U.S.C. § 103(A) OVER BURCHARD IN VIEW OF FRANCES, F. (FOOD SCIENCE AND TECHNOLOGY, 2<sup>ND</sup> ED, VOL 1, PP. 856-857, 2000).**

The Examiner rejected claims 1, 4, 5-7 as being unpatentable over Burchard in view of Frances.

Examiner states that Burchard fails to teach the claimed pH range of “between 7.5-7.9.” see OA at pg. 16, ¶1. Accordingly, Examiner relies on the teachings of Frances to state that pH adjusting agents are well-known in the food industry such as chemical leaving agents for baking. see OA at pg.16, ¶2. Accordingly, relying on the ruling in *In re Aller*, 220 F2d 454, 456 (CCPA 1955), Examiner concludes that discovering optimum or workable ranges involved only routine skill in the art and thus would have been obvious at the time of invention to determine all operable and optimal pH’s for each individual food prepared with pawpaw fruit. see *Id.* Examiner adds that pH is an art-recognized result effective variable which would have been routinely determined and optimized in the food art. see OA at pg. 16, ¶ 3.

Applicant respectfully submits that first the combined teachings of the cited references fail to meet all elements of the instant claims; and second, one of ordinary skill in the art would not have been motivated to use the cited references to reach the instantly claimed invention. Accordingly, for such reasons Applicant respectfully requests withdrawal of the pending rejections.

**A. THE COMBINED TEACHINGS OF THE CITED REFERENCES FAIL TO MEET ALL ELEMENTS OF THE INSTANT CLAIMS**

It has been well established that in determining the propriety of the Patent Office case for obviousness the combined teachings of the references must meet every element of the pending

claims. Here, not only has the Examiner failed to provide an adequate showing of the claimed elements in the cited reference, but also failed to offer a legal conclusion of obviousness that teaches all the elements of the instant claims.

At page 14, lines 1-2 of the Office Action, Examiner states that “the term ‘mild base’ as recited by the claims is very broad. It is deemed that water is a ‘mild base’..” Aside from the fact that water is not a mild base, Applicant have amended the claims to better clarify the scope of the term “mild base.” Accordingly, as amended, the present claims are directed to such bases that have a pKa of below 11. Since water has a pKa of about 15, the primary reference relied upon fails to teach the claimed limitations.

Examiner then correctly asserts that Burchard does not teach a pH range of between about 7.5 to about 9.5. Although the Examiner relies on Frances to remedy the short comings of Burchard, the argument ultimately relies on the common knowledge or understanding in the art to reach the claimed pH limitations.

It has been well settled that it is never appropriate to rely solely on “common knowledge” in the art without evidentiary support in the record, as the principal evidence upon which a rejection is based. MPEP 2144.03(A), *see also In re Zurko*, 258 F.3d 1379, 1385 (Fed. Cir. 2001). Conclusionary statements such as ones made here do not fulfill the legal test required for an obviousness analysis.

Here, the claimed invention as amended is now directed to the use of specific base for the claimed final product. The combined teachings of the references do not teach such limitations. There are absolutely no hints in the prior art as to the preferred pKa of base. Indeed, as discussed above, Burchard is concerned with the preparation of an acidic food product and actually teaches the addition of acidic ingredients such as lime juice and not bases, mild or otherwise.. Thus, the combination of the teachings suggested by the Examiner does not meet all elements of the pending claims. For such reasons alone, this rejection should be withdrawn.

**B. THERE IS NO TEACHINGS, SUGGESTIONS OR MOTIVATION FOR ORDINARY SKILL IN THE ART TO USE OR COMBINE THE CITED REFERENCES TO REACH THE INSTANTLY CLAIMED INVENTION**

The Court of Appeals for the Federal Circuit has repeatedly ruled that “obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teachings, suggestion, or motivation to do so.” *In re*

*Kahn*, 441 F.3d 997, 986 (Fed. Cir. 2006). Even if all aspect of the claimed invention were described in the cited references “[it would not be] sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references.” *In re Kotzab*, 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1318 (Fed. Cir. 2000). The combined teachings of the references does not meet such requirements.

Applicant adds that the recent Supreme Court Decision, *KSR v. Teleflex*, did not abolish the requirement for showing a motivation to combine multiple references. 127 S. Ct. 1727 (2007). Specifically, the Court cautioned against an improper hindsight stating that “patent composed of several elements is not proved obvious merely by demonstrating that each element was, independently, known in the prior art.” *Id.* at 1731. The Court further restated that:

it can be important to identify a reason that would have prompted a person of ordinary skill in the art to combine the elements as the new invention does. Inventions usually rely upon building blocks long since uncovered, and claimed discoveries almost necessarily will be combinations of what, in some sense, is already known.

*Id.* Accordingly, the *KSR* decision still requires that the Examiner to show some motivation or articulate some reason to combine the references.

In the instant case, there is no motivation, teachings or suggestions to modify the pH of those products taught by Burchard to conform with such limitations in the instant invention. The role of pH in food industry is not as trivial as Examiner has suggests. There is no reason for those of ordinary skill in the art of food industry to modify the pH for sake of reaching an optimal pH between ranges 7.5-9.5. In fact, even if one of ordinary skill in the art has a desire to optimize the pH of a food product, it would not exceed the value of about 5.

Applicant states that 21 C.F.R. § 110-114 strictly describes the required pH levels for manufacturing and preserving food products. *see* Exhibit 3. The Examiner’s attention is drawn to § 110.80(b)(2), wherein during the manufacturing process, the manufacturer must “comply with the requirement is careful monitoring of physical factors such as time... pH ....to ensure that mechanical breakdowns... do not contribute to the decomposition or contamination of food.” Measurements such as “controlling pH” are necessary to destroy, avoid or prevent the growth of undesirable microorganisms. *see* 21 C.F.R. §110.80 (b)(4). To achieve such goal, a manufacturer must maintain the “pH of 4.6 or below” to comply with the regulations. *see* 21 C.F.R. § 110.80(b)(15).

In fact for acidified foods, such as those described by Burchard, i.e. jelly and jams, strict control and testing is require to ensure that “finished equilibrium pH values....are not higher than 4.6.” *see* 21 C.F.R. § 114.3(b) and 114.80(a)(2). Therefore, contrary to the Examiner’s assertion, there is no motivation to optimize Burchard’s food product to any pH above 4.6. Indeed, the cited art teaches away from the limitations of the claims. One of ordinary skill in the art would not be motivated to modify the pH of the Burchard’s final product to those ranges instantly claimed, because to do so would violate the standards employed by the industry. Even assuming that such modification was possible, there is no motivation in the art to make any such pH adjustments in the amounts employed in the instant invention.

In summary, the Examiner has failed to provide any motivation in the art to make the modifications prescribed. But further, even assuming *arguendo* that there exists some motivation in the art, the suggested modifications still do not teach all elements of the instant claims. Accordingly, Applicant respectfully requests withdrawal of the instant rejection.

**VII. REJECTION UNDER 35 U.S.C. § 103(A) OVER BURCHARD IN VIEW OF ALLEY L. REPORTING FOR THE SAN DIEGO UNION TRIBUNE 2002.**

The Examiner has rejected 1-4, and 6 as being unpatentable over Burchard in view of Alley. The Examiner states that Burchard does not teach a method of straining a jelly composition but Alley teaches such straining step. Accordingly the Examiner concludes that it would have been obvious to filter or strain the composition before sale to remove larger amounts of fibrous pulp in the jam. *see* OA pg. 16.

Again, as argued above, Burchard fails to meet various limitations instantly claimed. Nevertheless, assuming *arguendo* that cited references are combinable, their combined teachings still does not meet all the limitations of the instant claims. As indicated above, neither Burchard nor Alley describe the pKa limitations of the product and process. Accordingly, the rejection is improper and should be withdrawn.

**CONCLUSION**

Applicants respectfully request withdrawal of the pending rejection and issuance of a Notice of Allowance. Should any fees be due, the USPTO is authorized to charge Deposit Account No. 50-1943 for any charges in connection with this matter.

Applicants believe that this application is in a condition for allowance and an early notice to this effect is earnestly solicited. Should the Examiner have any questions or comments with respect to this Response, it is respectfully requested that the Examiner telephone Applicants' attorney at (609) 844-3030 to discuss any additional matters.

Respectfully submitted,

Date: February 7, 2008

/ Shahnam Sharareh /

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Shahnam Sharareh, PharmD, Esq.  
Registration No. 59,040  
Attorney for the applicant  
Fox Rothschild LLP  
Princeton Pike Corporate Center  
997 Lenox Drive, Building 3  
Lawrenceville, NJ 08648-2311  
Telephone: (609) 844-3030  
Facsimile: (609) 896-1469